

Practitioner's Docket No. MPI03-025P1RNM

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Re application of: Xu, Haiyan, et al.

Application No.: 10/764,649

Group No.: 1646

Filed: January 26, 2004

Examiner: Howard, Zachary C.

For: METHODS AND COMPOSITIONS FOR USE OF INFLAMMATORY PROTEINS  
IN THE DIAGNOSIS AND TREATMENT OF METABOLIC DISORDERS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT  
IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING  
INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed:

☒ Within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

**OR**

☐ *After* three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but *before* the mailing date of either:

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**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***

I hereby certify that, on the date shown below, this correspondence is being:

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**37 C.F.R. SECTION 1.8(a)**

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Date: February 17, 2005

Sean Hunziker  
(type or print name of person certifying)

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**Practitioner's Docket No. MPI03-025P1RNM**

- (1) a final action under Section 1.113,
- (2) a notice of allowance under Section 1.311, or
- (3) an action that otherwise closes prosecution in the application

whichever occurs first.

[ ] Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

[ ] Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

[ ] No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

**OR**

[ ] The information disclosure statement transmitted herewith is being filed *after* a final action under Section 1.113, or a notice of allowance under Section 1.311, whichever occurs first, but before, or simultaneously with, the payment of the issue fee.

[ ] In accordance with the requirements of 37 C.F.R. Section 1.97(d):

A. [ ] Accompanying this transmittal is the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

B. [ ] Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(1).

C. [ ] No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and to the knowledge of the person signing the statement after making reasonable inquiry, was known to any individual designated in Section 1.56(c) more than three months prior to the filing of the information disclosure statement. 37 C.F.R. Section 1.97(e)(2).

Practitioner's Docket No. MPI03-025P1RNM

**FEE PAYMENT**

3. ☐ The fee due is set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

☒ Applicant believes no fee is due in connection with this submission.

Fee due \$0.00

**METHOD OF PAYMENT OF FEE**

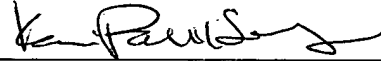
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☐ Charge Account No. 501668 in the amount of \$0.00 .  
☒ A duplicate of this request is attached.

If any additional fees are due, please charge Account 501668.

February 17, 2005

MILLENNIUM PHARMACEUTICALS, INC.

By



Kerri Pollard Schray  
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**INFORMATION DISCLOSURE STATEMENT**

**List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

1. ☒ Preliminary Statements
2. ☒ Form PTO/SB/08B (substitute for Form PTO-1449) (3 pages)
3. ☒ Copies of Listed Information Items Accompanying This Statement (22 references)

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**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***

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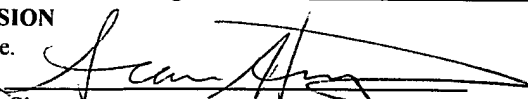
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**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

  
Signature

Date: February 17, 2005

Sean Hunziker  
(type or print name of person certifying)

**Preliminary Statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

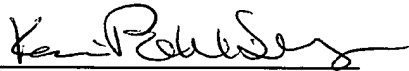
The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Copies of Listed Information Items Accompanying This Statement**

Legible copies of all items listed in Form PTO/SB/08B (substitute for Form PTO-1449) accompany this information statement.

February 17, 2005

MILLENNIUM PHARMACEUTICALS, INC.

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| Substitute for form 1449B/PTO   |   | FEB 22 2005 |   | <b>Complete if Known</b>      |                    |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |             |   | <b>Application Number</b>     | 10/764,649         |
|   |   |             |   | <b>Filing Date</b>            | January 26, 2004   |
|   |   |             |   | <b>First Named Inventor</b>   | Xu, Haiyan, et al. |
|   |   |             |   | <b>Group Art Unit</b>         | 1646               |
|   |   |             |   | <b>Examiner Name</b>          | Howard, Zachary C. |
| <b>Sheet</b>  | 1 | <b>of</b>   | 3 | <b>Attorney Docket Number</b> | MPI03-025P1RNM     |

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published. | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
|                    | C1                    | Nishina, P.M. <i>et al.</i> (1994), <i>Metab.</i> 43:554-558  |                |
|                    | C2                    | Grundy, S. M. & Barnett, J.P. (1990), <i>Dis. Mon.</i> 36:641-731   |                |
|                    | C3                    | Kahn <i>et al.</i> , (1996) <i>Annu. Rev. Med.</i> 47:509-531   |                |
|                    | C4                    | Friedman, J. M. <i>et al.</i> (1991) <i>Mamm. Gen.</i> 1:130-144  |                |
|                    | C5                    | Friedman, J. M. and Liebel, R. L. (1992) <i>Cell</i> 69:217-220   |                |
|                    | C6                    | Bray, G. A. (1989) <i>Amer. J. Clin. Nutr.</i> 5:891-902  |                |
|                    | C7                    | Chen, H. <i>et al.</i> (1996) <i>Cell</i> 84:491-5  |                |
|                    | C8                    | Chua SC Jr <i>et al.</i> (1996) <i>Science</i> 271:994-6  |                |
|                    | C9                    | Lee, G.H. <i>et al</i> (1996) <i>Nature</i> 379:632-5   |                |
|                    | C10                   | MacDougald, O.A. <i>et al</i> (1995) <i>Proc. Natl. Acad. Sci. USA</i> 92:9034-7  |                |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation design number. <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |                               | <b>Application Number</b>   | 10/764,649         |
|   |                               | <b>Filing Date</b>          | January 26, 2004   |
|   |                               | <b>First Named Inventor</b> | Xu, Haiyan, et al. |
|   |                               | <b>Group Art Unit</b>       | 1646               |
|   |                               | <b>Examiner Name</b>        | Howard, Zachary C. |
| Sheet 2 of 3  | <b>Attorney Docket Number</b> | MPI03-025P1RN               |                    |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|--|-----------------------|---|----------------|
| Examiner Initials*                                 | Cite No. <sup>1</sup> | Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published. | T <sup>2</sup> |
|  | C11                   | Stubdal H. <i>et al.</i> (2000) <i>Mol. Cell Biol.</i> 20(3):878-82   |                |
|  | C12                   | Abadie J.M. <i>et al.</i> <i>Lipids</i> (2000) 35(6):613-20   |                |
|  | C13                   | Shaughnessy S. <i>et al.</i> (2000) <i>Diabetes</i> 49(6):904-11  |                |
|  | C14                   | Loskutoff D.J. <i>et al.</i> (2000) <i>Ann. N. Y. Acad. Sci.</i> 902:272-81   |                |
|  | C15                   | Alleva <i>et al.</i> (2001) <i>J. Clin. Invest.</i> 107:173-180   |                |
|  | C16                   | Arakawa <i>et al.</i> (2001) <i>Br. J. Pharmacol.</i> 132:578-586   |                |
|  | C17                   | Nakamura <i>et al.</i> (2001) <i>Diabetes Res. Clin. Pract.</i> 51:9-20   |                |
|  | C18                   | O'Harte <i>et al.</i> (2001) <i>Regul. Pept.</i> 96:95-104  |                |
|  | C19                   | Yamanouchi <i>et al.</i> (2000) <i>Exp. Anim.</i> 49:259-266  |                |

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PTO/SB/08B (10-96)

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| <b>Substitute for form 1449B/PTO</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |           |   | <b>Complete if Known</b>      |                    |
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|   |   |           |   | <b>Attorney Docket Number</b> | MPI03-025P1RN      |
| <b>Sheet</b>  | 3 | <b>of</b> | 3 |                               |                    |

| <b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b> |                                 |  |                      |
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| <b>Examiner<br/>Initials*</b>                             | <b>Cite<br/>No.<sup>1</sup></b> | <b>Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.</b> | <b>T<sup>2</sup></b> |
|   | C20                             | Hoenig <i>et al.</i> (2000) <i>Am. J. Pathol.</i> 157:2143-2150  |                      |
|   | C21                             | Reed <i>et al.</i> (2000) <i>Metabolism</i> 49:1390-1394   |                      |
|   | C22                             | Clark <i>et al.</i> (2000) <i>J. Pharmacol. Toxicol. Methods</i> 43:1-10   |                      |
|   |                                 |  |                      |
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|                               |  |                            |  |
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